

REMARKS RELATING TO THE OFFICE ACTION
MAILED OCTOBER 18, 2005

Claim Objections

In the Office Action of October 18, 2005, the Examiner objected to Claim 52, as being of improper dependent form for failing to further limit the subject matter of a previous claim. New claim 114, clearly states that the tissue may be irradiated specifically with ionizing radiation. Applicants request that this objection not be applied to new claim 114.

Rejection under 35 USC § 112, Second Paragraph

In the Office Action of October 18, 2005, the Examiner rejected Claims 49-61, 63-65, and 73-109 under 35 USC § 112, Second Paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention. Specifically, the Examiner asserted that independent Claim 49, and dependent Claims 50-61, 63-65, and 73-109 were indefinite because Claim 49 recites a method of preparing a tissue "with reduced tissue damage" without providing a point of reference. According to the Examiner, the term "reduced" is a relative term and, as such is indefinite in the absence of a specific comparison. Applicants request that this rejection not be applied against new claims 111-163.

New claim 111 does not include the relative term "reduced." Applicants point out that new claim 111 does not introduce new matter and does not broaden previous claim 49 because it is clear from the specification that Applicants' method, as defined by claim 111, and claims depended therefrom, is directed to preparing a tissue with reduced tissue damage, as compared to tissue prepared according to the conventional methods, including uncontrolled rate freezing, freeze drying, and glutaraldehyde preservation methods. See specification, for example, at page 4, paragraph [0009] and page 24, paragraph [0072].

Given the above, Applicants respectfully request that 35 U.S.C. § 112, Second Paragraph rejection of Claims 49-61, 64, and 73-109 not be applied against new claim 111-163.

Rejection under 35 USC § 103

In the Office Action of October 18, 2005, claims 49, 50, 52-61, 63-65, 73, 81-90, 98, 101-106, and 108 were rejected under 35 USC § 103(a) as being unpatentable over US 5,328,821 to Fisher *et al.* (Fisher *et al.*) taken in view of US 4,798,611 to Freeman, Jr. (Freeman, Jr.). Also, Claims 49-61, 63-65, and 73-109 were rejected under 35 USC § 103(a), as obvious over Fisher *et al.*, taken in view of Freeman, Jr., and further in view of US 5,677,019 to Carstairs *et al.* (Carstairs *et al.*), US 6,140,123 to Demetriou *et al.* (Demetriou *et al.*), US 4,155,331 to Lawrence *et al.* (Lawrence *et al.*), US 5,279,964 to Christope (Christope), and US 5,403,834 to Malfroy-Camine *et al.* (Malfroy-Camine *et al.*). Applicants request that this rejection not be applied against new claims 111-163.

The Examiner admits at page 3, last line, of the Office Action of October 18, 2005 that the Fisher *et al.* reference does not teach irradiating the tissue at any time. The Examiner asserts that Freeman, Jr. teaches irradiating the tissue. The Examiner further asserts that although the Freeman, Jr. reference teaches crosslinking prior to irradiation, Applicants' claims do not exclude the embodiments in which the tissue is crosslinked prior to irradiation. The Examiner concluded that it would have been obvious to use the irradiation step of Freeman, Jr. on the tissue of Fisher *et al.*

The present invention, as defined by independent claim 111 and dependent claims 112-163, is directed to a method of preparing a tissue, including providing an uncrosslinked tissue; providing a solution comprising water, a bio-compatible buffer, a cell-impermeant constituent, a cell-permeant constituent, and a radical scavenger; and combining the solution with the tissue. The method also includes lowering the temperature of said solution and said tissue to at least the freezing point of the solution; and irradiating the solution and the tissue. As described throughout the specification, including for example, at

page 18, paragraph [0055], the solution used in the method as recited in Applicants' claims provides described tissue benefits as compared to conventional solutions.

The previously applied Fisher *et al.* and Freeman, Jr. references, alone or in combination, do not teach or suggest each and every element of Applicants' new claims. For example, neither Fisher *et al.* nor Freeman, Jr., alone or in proper combination, teach a method, as defined by Applicants' new independent claim 111, and new dependent claims 112-163. More specifically, neither Fisher *et al.* nor Freeman, Jr. disclose a method of preparing a tissue including irradiating uncrosslinked tissue.

Moreover, because the method described by Freeman, Jr. is directed at sterilizing pre-crosslinked tissue, the method, in fact, teaches away from Applicants' invention by requiring crosslinking of tissue using, for example, glutaraldehyde, prior to the irradiation step. In contrast, the method of Applicant's invention requires that the uncrosslinked tissue be combined with a solution in a method of preparing a tissue. Consequently, a combination of the Fisher *et al.* and Freeman, Jr. references would result in tissue that has been crosslinked and cryopreserved. As such, this combination, even if proper, would not have made Applicants' invention obvious.

Accordingly, previous rejection of claims 49, 50, 52-61, 63-65, 73, 81-90, 98, 101-106, and 108 under 35 U.S.C. §103 over Fisher *et al.* in view of Freeman, Jr., should not be applied against Applicants' new claims 111-163.

Furthermore, as admitted by the Examiner in the Office Action of October 18, 2005, neither Fisher *et al.* nor Freeman, Jr. addresses each and every element of the solutions used in the method of Claims 49-61, 63-65, and 73-109 (See Office Action of October 18, 2005, page 7, lines 1-3 from the end). As described above, the Fisher *et al.* reference does not disclose a method of preparing a tissue including irradiating an uncrosslinked tissue. Nothing in the Freeman, Jr., Carstairs *et al.*, Demetriou *et al.*, Lawrence *et al.*, Christope, and Malfroy-Camine *et al.* references suggests modifying the method to produce an uncrosslinked irradiated tissue of Applicants' new claim 111. Because the

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method of Applicants' claim 111 is novel and non-obvious, any claim depending from claims 111 would also be novel and non-obvious and as such this rejection should not be applied to new claims 111-163.

For these reasons, previous rejection of claims 49-61, 63-65, and 73-109 under 35 U.S.C. §103 over Fisher *et al.*, taken in view of Freeman, Jr., and further in view of Carstairs *et al.*, Demetriou *et al.*, Lawrence *et al.*, Christope, Malfroy-Camine *et al.*, should not be applied against new claims 111-163.

CONCLUSION

Applicants respectfully submit that the present application is now in condition for examination. Should the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,

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